Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of group counseling with telephone counseling on Diet and Physical Activity among middle-aged women in Mehriz

Protocol summary

Study aim

The aim of this study is to compare the effect of group counseling with telephone counseling on the nutritional status and physical activity of middle-aged women.

Design

This study is a randomized clinical trial study

Settings and conduct

The research population will be all middle-aged women of mehriz City, which will be selected using purposeful sampling method of Hosseinieh and mosques of this city.The sample size is 75. The samples are randomly divided into three groups (two intervention groups and one control group.three groups will be evaluated at the time of intervention (before) and immediately after the intervention and one month after the intervention with the health promotion lifestyle profile questionnaire of middle-aged women

Participants/Inclusion and exclusion criteria

Inclusion criteria: informed consent, ages 40-60 and access to the telephone and exclusion criteria: having hearing and speaking problems and the presence of severe or debilitating physical or mental illnesses that would prevent the person from attending the program

Intervention groups

The sample size is 75. The samples will be divided into three groups (two intervention groups and one control group) using the random numbers table.persons in group counseling group will receive a group counseling (for 2 hours) for a period of 4 weeks. Persons in the telephone counseling group will receive a total of 8 telephone counseling calls twice a week for a period of four weeks, (30 minutes). The two groups will be free to call and visit. During this period no advice will be given to the control group.

Main outcome variables

Nutritional status and Physical activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180111038310N1**
Registration date: **2018-04-28, 1397/02/08**
Registration timing: **retrospective**

Last update: **2018-04-28, 1397/02/08**
Update count: **0**

Registration date

2018-04-28, 1397/02/08

Registrant information

Name

Behnaz Rahbarnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3824 1751

Email address

behnaz@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-22, 1396/06/31

Expected recruitment end date

2017-12-20, 1396/09/29

Actual recruitment start date

2017-09-22, 1396/06/31

Actual recruitment end date

2017-11-18, 1396/08/27

Trial completion date

empty

Scientific title

Comparison of group counseling with telephone counseling on Diet and Physical Activity among middle-aged women in Mehriz

Public title
Comparison of group counseling with telephone counseling on Diet and Physical Activity in middle-aged women in Mehriz
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Informed Consent Ages 40-60 Phone Access
Exclusion criteria:
The presence of severe or debilitating physical or mental illnesses that would prevent the person from attending the program Have a hearing and speaking problem
Age
From **40 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **75**
Actual sample size reached: **71**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling is done using random numbers table
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Sadoughi University of Medical Sciences Yazd
Street address
Yazd, Bahonar Square, Central building of Shahid Sadoughi University of Medical Sciences, Yazd
City
Yazd
Province
Yazd
Postal code
8916978477

Approval date
2017-08-01, 1396/05/10
Ethics committee reference number
IR.SSU.REC.1396.90

Health conditions studied

1

Description of health condition studied
Nutrition status and physical activity
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Nutrition status score
Timepoint
Before intervention, after intervention and 1 month after intervention
Method of measurement
Health promotion life style questionnaire for middle-aged women

2

Description
Physical activity score
Timepoint
Before intervention, after intervention and 1 month after intervention
Method of measurement
Health promotion life style questionnaire for middle-aged women

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group counseling 4 sessions with weekly intervals
Category
Lifestyle

2

Description
Intervention group: Telephone counseling 8 phone calls, twice a week
Category
Lifestyle

3

Description
Control group: No intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Hosseinieh and mosques
Full name of responsible person
Behnaz Rahbarnia
Street address
Mehriz
City
Yazd
Province
Yazd
Postal code
8981646589
Phone
+98 35 3824 1751
Email
bn.rahbarnia@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Sadoughi University of Medical Sciences, Yazd
Full name of responsible person
Dr. Amir Houshang Mehrparvar
Street address
Yazd, Bahonar Square, Headquarters of Yazd University of Medical Sciences
City
Yazd
Province
Yazd
Postal code
8916978477
Phone
+98 35 3146 2136
Email
ah.mehrparvar@gmail.com
Web page address
http://www.ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Sadoughi University of Medical Sciences, Yazd
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Behnaz Rahbarnia
Position
Student of MSc in Midwifery Counseling
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Yazd, Safayee, Bou Ali Avenue, Nursing and Midwifery University
City
Yazd
Province
Yazd
Postal code
8949147553
Phone
+98 35 3824 1751
Email
bn.rahbarnia@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Behnaz Enjezab
Position
Associate Professor in reproductive health
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Yazd, Safayeh, itimsar Fallahi St., Bouali Sinai Alley, Nursing and Midwifery University
City
Yazd
Province
Yazd
Postal code
8949147553
Phone
+98 35 3824 1751

Email
enjezabbehnaz@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Behnaz Rahbarnia

Position
Student of MSc in Midwifery Counseling

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Yazd, Safayeh, timsar Fallahi St., Bouali Sinai Alley, Nursing and Midwifery University

City
Yazd

Province
Yazd

Postal code
8949147553

Phone
+98 35 3824 1751

Email
bn.rahbarnia@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable